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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,902	05/15/2006	Jeffrey B. Kaplan	UMD-0111	8859
46046	7590	05/24/2007		
LICATA & TYRRELL P.C. 66 EAST MAIN STREET MARLTON, NJ 08053			EXAMINER SLOBODYANSKY, ELIZABETH	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 05/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,902

Applicant(s)

KAPLAN, JEFFREY B.

Examiner

Elizabeth Slobodyansky, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/US03/34683 published as WO 04/61117 on July 22, 2004.

The preliminary amendment filed June 14, 2005 amending claims 2-4 has been entered.

Claims 1-34 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to a nucleic acid encoding β -N-acetylglucosaminidase, a vector and a host cell comprising thereof.

Group II, claim(s) 7-11 and 15, drawn to a β -N-acetylglucosaminidase and a liquid antiseptic composition comprising thereof.

Group III, claim(s) 12 and 26-31 (in part), drawn to methods of treatment of an organism by administering β -N-acetylglucosaminidase.

Group IV, claim(s) 13 and 14, drawn to a medical device coated with β -N-acetylglucosaminidase.

Group V, claim(s) 16, drawn to method of mutating a *dspB* gene.

Group VI, claim(s) 17, drawn to a method of use of an inhibitor.

Group VII, claim(s) 18 and 19, drawn to a mutant of *Actinobacillus actinomycetemcomitans*.

Group VIII, claim(s) 20 and 21, drawn to a method for identifying a modulator of activity, level or expression of β -N-acetylglucosaminidase.

Group IX, claim(s) 22-25, drawn to a method of treatment of a device by using β -N-acetylglucosaminidase.

Group X, claim(s) 26-31 (in part), drawn to a method of treatment of an organism by administering a nucleic acid encoding β -N-acetylglucosaminidase.

Group XI, claim(s) 32-34, drawn to a primer pair and a kit.

For each of inventions I-XI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-XI and one of inventions (A)-(E).

- (A). SEQ ID No: 2 or a sequence encoding SEQ ID No: 2.
- (B). SEQ ID No: 4 or a sequence encoding SEQ ID No: 4.
- (C). SEQ ID No: 6 or a sequence encoding SEQ ID No: 6.
- (D). SEQ ID No: 8 or a sequence encoding SEQ ID No: 8.
- (E). SEQ ID No: 10 or a sequence encoding SEQ ID No: 10.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions listed as (A)-(E), represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

A special technical feature of Groups II, III, VIII and IX is a β -N-acetylglucosaminidase. Its sequence is determined by the structure of an encoding DNA which thus has a corresponding special technical feature (Groups I, VIII, X)). Nucleic acids encoding the β -N-acetylglucosaminidase of Group II are known in the art according to PCT Search Report (form PCT-210). Therefore, the inventions of Groups I-III and VIII-X do not share a special technical feature and each, considered as a whole, does not make a contribution over the prior art.

Inventions I and II do not share a special technical feature because they are drawn to different compounds each with its own chemical structure and function, and they have different utilities. While a polypeptide of invention II can be used for the production of an antibody, a nucleic acid of invention I can be used not only for the production of β -N-acetylglucosaminidase but as a hybridization probe as well.

Inventions of Groups I and XI do not share a special technical feature because they have different structures, functions and utilities. A nucleic acid of invention I encodes β -N-acetylglucosaminidase while the primers of Group XI do not. Inventions of Groups I, II and Group VI do not share a special technical feature because they are drawn to different compounds each with its own chemical structure and function, and they have different utilities. The structure of a modulator used in invention of Group VI is unpredictable from the structure of β -N-acetylglucosaminidase. Inventions I-II and

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invention VII do not share a special technical feature because the inventions of Groups I-II are isolated chemical compounds whereas the invention of Group VII is a live organism comprising a great number of compounds acting in accord. Inventions II and IV do not share a special technical feature because the invention of Group II is an isolated chemical compound whereas the invention of Group IV comprises a device comprising various parts that represent its special technical feature.

Inventions III, V, VI and VIII-X do not share a special technical feature because they are drawn to methods of use of different compounds such as β -N-acetylglucosaminidase, its modulator and a nucleic acid encoding thereof. Said methods have different protocols and utilities.

Inventions III and VIII-IX do not share a special technical feature because they are drawn to methods of *in vivo* and *in vitro* use of β -N-acetylglucosaminidase. Said methods have different protocols and utilities.

37 CFR 1.475 does not provide for multiple products or methods within one application. Therefore, unity is lacking with regard to inventions I-XI.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, reading "E. Slobodyansky". The signature is written in a cursive style with a long, sweeping tail on the "y".

Elizabeth Slobodyansky, PhD
Primary Examiner
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May 21, 2007